Telehealth: Understanding the Basics and the Recent COVID-19 Related Changes

May 21, 2020

3:00 – 4:00 p.m.

CT Bar Association

Webinar

CT Bar Institute, Inc.

CT: 1.0 CLE Credit (General)

Lawyers' Principles of Professionalism

As a lawyer I must strive to make our system of justice work fairly and efficiently. In order to carry out that responsibility, not only will I comply with the letter and spirit of the disciplinary standards applicable to all lawyers, but I will also conduct myself in accordance with the following Principles of Professionalism when dealing with my client, opposing parties, their counsel, the courts and the general public.

Civility and courtesy are the hallmarks of professionalism and should not be equated with weakness;

I will endeavor to be courteous and civil, both in oral and in written communications;

I will not knowingly make statements of fact or of law that are untrue;

I will agree to reasonable requests for extensions of time or for waiver of procedural formalities when the legitimate interests of my client will not be adversely affected;

I will refrain from causing unreasonable delays;

I will endeavor to consult with opposing counsel before scheduling depositions and meetings and before rescheduling hearings, and I will cooperate with opposing counsel when scheduling changes are requested;

When scheduled hearings or depositions have to be canceled, I will notify opposing counsel, and if appropriate, the court (or other tribunal) as early as possible;

Before dates for hearings or trials are set, or if that is not feasible, immediately after such dates have been set, I will attempt to verify the availability of key participants and witnesses so that I can promptly notify the court (or other tribunal) and opposing counsel of any likely problem in that regard;

I will refrain from utilizing litigation or any other course of conduct to harass the opposing party;

I will refrain from engaging in excessive and abusive discovery, and I will comply with all reasonable discovery requests;

In depositions and other proceedings, and in negotiations, I will conduct myself with dignity, avoid making groundless objections and refrain from engaging I acts of rudeness or disrespect;

I will not serve motions and pleadings on the other party or counsel at such time or in such manner as will unfairly limit the other party's opportunity to respond;

In business transactions I will not quarrel over matters of form or style, but will concentrate on matters of substance and content;

I will be a vigorous and zealous advocate on behalf of my client, while recognizing, as an officer of the court, that excessive zeal may be detrimental to my client's interests as well as to the proper functioning of our system of justice;

While I must consider my client's decision concerning the objectives of the representation, I nevertheless will counsel my client that a willingness to initiate or engage in settlement discussions is consistent with zealous and effective representation;

Where consistent with my client's interests, I will communicate with opposing counsel in an effort to avoid litigation and to resolve litigation that has actually commenced;

I will withdraw voluntarily claims or defense when it becomes apparent that they do not have merit or are superfluous;

I will not file frivolous motions;

I will make every effort to agree with other counsel, as early as possible, on a voluntary exchange of information and on a plan for discovery;

I will attempt to resolve, by agreement, my objections to matters contained in my opponent's pleadings and discovery requests;

In civil matters, I will stipulate to facts as to which there is no genuine dispute;

I will endeavor to be punctual in attending court hearings, conferences, meetings and depositions;

I will at all times be candid with the court and its personnel;

I will remember that, in addition to commitment to my client's cause, my responsibilities as a lawyer include a devotion to the public good;

I will endeavor to keep myself current in the areas in which I practice and when necessary, will associate with, or refer my client to, counsel knowledgeable in another field of practice;

I will be mindful of the fact that, as a member of a self-regulating profession, it is incumbent on me to report violations by fellow lawyers as required by the Rules of Professional Conduct;

I will be mindful of the need to protect the image of the legal profession in the eyes of the public and will be so guided when considering methods and content of advertising;

I will be mindful that the law is a learned profession and that among its desirable goals are devotion to public service, improvement of administration of justice, and the contribution of uncompensated time and civic influence on behalf of those persons who cannot afford adequate legal assistance;

I will endeavor to ensure that all persons, regardless of race, age, gender, disability, national origin, religion, sexual orientation, color, or creed receive fair and equal treatment under the law, and will always conduct myself in such a way as to promote equality and justice for all.

It is understood that nothing in these Principles shall be deemed to supersede, supplement or in any way amend the Rules of Professional Conduct, alter existing standards of conduct against which lawyer conduct might be judged or become a basis for the imposition of civil liability of any kind.

--Adopted by the Connecticut Bar Association House of Delegates on June 6, 1994

JODY ERDFARB

COUNSEL

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EDUCATION

J.D., University of Connecticut School of Law
With Honors

B.A., Yeshiva University
summa cum laude

ADMISSIONS

Connecticut
New York

Jody is Counsel in Wiggin and Dana's Health Care Department, where she advises a wide range of health care organizations such as hospitals, long-term-care providers, dental practices, behavioral health clinics, individual practitioners, and information technology companies. She advises on a broad range of issues, including compliance, fraud and abuse, False Claims Act, HIPAA, patient care, regulatory, and corporate matters.

Jody relies on her broad range of knowledge to provide clients with the best possible support. Her experience includes assisting providers with state and federal survey issues, including handling compliance and informal dispute resolution meetings and appealing deficiencies with the Centers for Medicare and Medicaid Services; managing Medicaid audits; and responding to governmental subpoenas. She assists clients in developing and evaluating corporate compliance programs, HIPAA policies, and managing compliance issues, including conducting internal investigations, submitting self-disclosures, and negotiating with government authorities.

Jody is actively involved in the health law community. She is a member of the American Health Lawyer's Association (AHLA), the Connecticut Health Lawyer's Association, the American Bar Association (ABA) Health Law section, the International Association of Privacy Professionals (IAPP), and the Health Care Compliance Association (HCCA). She is the AHLA Vice Chair for the Health Information Technology Practice Group's Digital Health Records Affinity Group and is on the editorial board of the AHLA's Federal Healthcare Laws & Regulations. Jody formerly served on the ABA Health Law Section's taskforce on HITECH and in the AHLA's Leadership Development Program and is an adjunct professor at Quinnipiac University School of Law.

Jody received her J.D. with honors from the University of Connecticut School of Law, where she was an Associate Editor of the *Connecticut Journal of International Law*, a Dean's Scholar, and the recipient of several CALI awards. Jody won first place in the school's annual Hastie Moot Court Competition for best brief.

Nick Mercadante is CEO of PursueCare (https://www.pursuecare.com), a technology-enabled addiction treatment and behavioral health services provider founded in 2019. PursueCare leverages ground-breaking low-bandwidth telehealth technology to provide 24x7 on-demand access to Medication-Assisted Treatment for Opioid Use Disorder in rural and underserved communities. Their smart phone app provides direct access to comprehensive addiction treatment services and can ship medications straight to the patient at home. PursueCare partners with community health centers, health systems, insurance plans, and self-funded employers to create transitional programs that rapidly triage patients into care at home during the COVID crisis.

Nick previously served as President and COO of MedOptions, a national provider of behavioral healthcare to long-term care. There, Nick led development of a first-of-its-kind telehealth program to serve rural facilities where traditional in-person staffing is challenging. Early in his career while serving in a business development role at Drugmax Inc., Nick developed a telehealth pharmacy kiosk for point-of-care consultations, before the company was eventually acquired by Walgreens.

Nick also operates a consulting firm advising on telehealth strategy, regulations, implementations, and acquisitions. Nick graduated from Tulane Law School and is licensed to practice law in CT, NJ, and TX. He is a member of the American College of Healthcare Executives, American Health Law Association, and the Health Care Compliance Association.

CONNECTICUT BAR ASSOCIATION

TELEHEALTH:

UNDERSTANDING THE BASICS AND THE RECENT COVID-19 RELATED CHANGES

May 21, 2020 3:00 pm EST

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DISCLAIMER

- This presentation is intended for educational purposes only and should not be construed as legal advice.

- You should seek independent legal advice for specific factual situations.

WHY TELEHEALTH?

ADVANTAGES OF TELEHEALTH

- Increases access to care
- Improves quality of care
- Reduces healthcare costs
- Enhances traditional face-to-face medicine
- Improves patient engagement and satisfaction
- Improves provider satisfaction

RULES AND OBSTACLES

- State Licensure
- Remote Prescribing
- Corporate Practice of Medicine
- Medical Malpractice
- State Telehealth Standards
- HIPAA/Privacy Laws
- Fraud and Abuse
- Medicare, Medicaid, and Private Payor Reimbursement

STATE LICENSURE

LICENSURE

General Rule:

The practitioner must be licensed in the state in which the patient is located

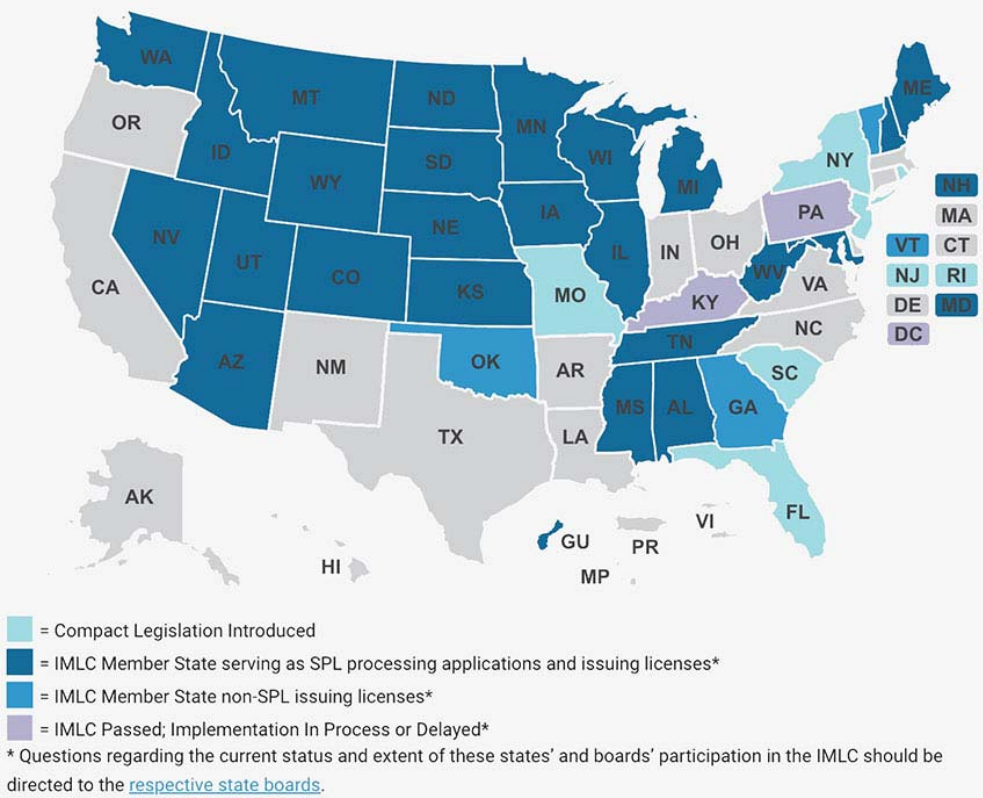
Exceptions:

- Physician to physician consult exception
- Infrequent consultation exception
- Special telemedicine licenses or certificates

Strategies to mitigate the licensure roadblock:

- State waivers
- Reciprocity statutes
- Interstate Medical Licensure Compact

Keep in mind scope of practice!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MP
= Compact Legislation Introduced
= IMLC Member State serving as SPL processing applications and issuing licenses*
= IMLC Member State non-SPL issuing licenses*
= IMLC Passed; Implementation In Process or Delayed*
* Questions regarding the current status and extent of these states' and boards' participation in the IMLC should be directed to the respective state boards.

COVID-19 WAIVERS

DPH Order (March 23, 2020); Executive Order 7DD (April 22, 2020); Extensions

Temporary suspension of the requirements for licensure, certification or registration to allow persons who are appropriately licensed, certified or registered in another state or territory of the United States or the District of Columbia to render temporary assistance in Connecticut within the scope of the profession for which the provider is licensed, certified or registered:

- EMS
- Medicine and Surgery
- Physical Therapists
- Nursing
- Nurse's Aides
- Respiratory Care Practitioners
- Psychologists
- Marital and Family Therapists
- Clinical Social Workers/Masters Social Workers
- Professional Counselors
- Pharmacy
- Occupational Therapist
- Alcohol and Drug Counselor
- Radiographer, Radiologic Technologist, Radiologist Assistant, Nuclear Medicine Technologists
- Dentist
- Dental Hygienist
- Behavior Analyst
- Genetic Counselor
- Music Therapist
- Art Therapist
- Dietician-Nutritionist
- Speech and Language Pathologist

REMOTE PRESCRIBING

PRESCRIBING

General CT Rule:

May prescribe "non-opioid" Schedule II & III controlled substances when treating psychiatric and substance use disorders. Otherwise follows federal Ryan Haight.

Ryan Haight Exceptions:

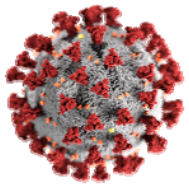
- First visit while patient at a DEA-qualifying facility or in presence of registered practitioner.
- Public health emergency
- Indian Health Service or tribal organization

Strategies for prescribing:

- Threshold in-person visit
- Medicaid "good cause" showing
- Must e-prescribe

What about the SUPPORT Act and Special Registration?

COVID-19



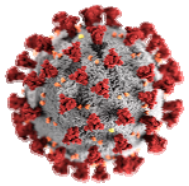
Connecticut: Follow the Federal
Federal: Declaration of Public Health Emergency declared by HHS

DEA Guidance: Ryan Haight exception to in-person requirement exists pertaining to all schedule II-V controlled substances as a result of public health emergency.

Effect: DEA-registered practitioners in all areas of US may prescribe controlled substances without an in-person evaluation provided the following are met:

- Legitimate medical purpose by registered practitioner otherwise qualified and within course of practice;
- telemedicine is conducted using audio-visual, real-time, two-way system; and
- otherwise acting in accordance with applicable Federal and State laws.

COVID-19



Additional DEA Guidance:

- Authorize remote identity proofing when e-prescribing (existed before COVID)
- Authorize prescribing across state lines without separate registration (DEA067 – March 25, 2020)
- Pharmacy regulations around inventories, shipping, and signing remain the same
- Narcotics Treatment Programs (NTPs) and MAT programs may prescribe and dispense longer take-home supply

Misconceptions/Contradictions:

- Has the DEA waived ordinary prescribing requirements? NO.
- Can practitioners prescribe controlled substances by phone? PROCEED CAUTIOUSLY.

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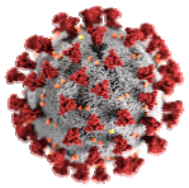
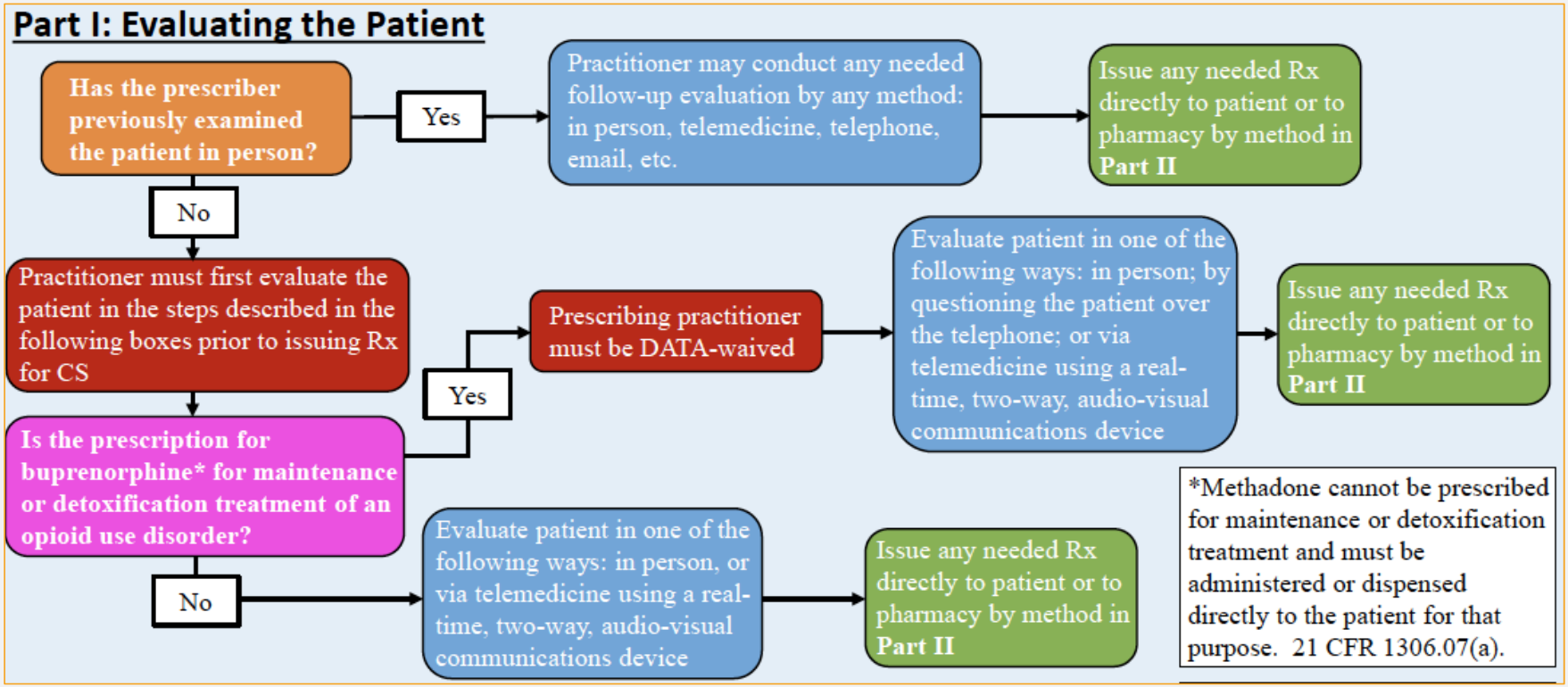
COVID-19



DEA Diversion Control (DEA075):



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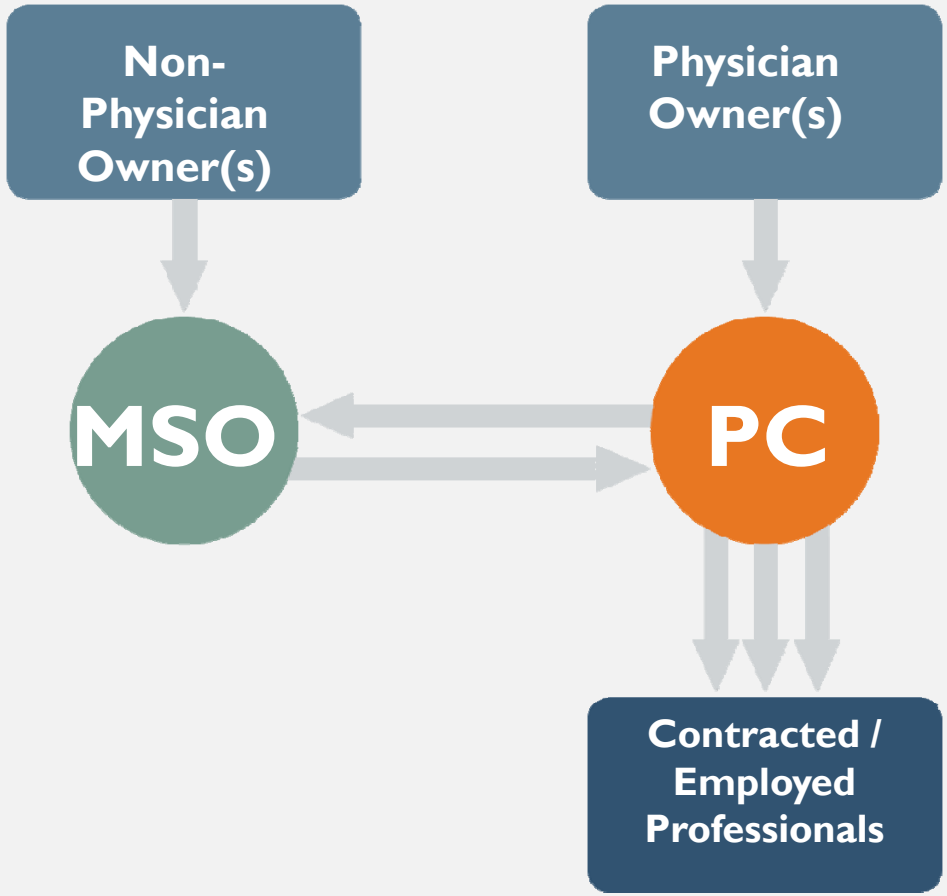
CORPORATE PRACTICE OF MEDICINE

CORPORATE PRACTICE OF MEDICINE

- Public policy limiting the practice of medicine to licensed physicians
- Prohibits businesses or corporations from practicing medicine or employing physicians to practice medicine
- Prohibits fee-splitting arrangements between physicians and non-physician entities or individuals
- Every state has its own approach to the corporate practice of medicine
- There are many strategies that can be employed to ensure compliance with states' corporate practice of medicine rules

"FRIENDLY" OR "CAPTIVE" PC MODEL



MEDICAL MALPRACTICE

MEDICAL MALPRACTICE INSURANCE

- Telemedicine providers should ensure that their malpractice coverage:
  - covers telemedicine services
  - coverage extends to services provided to residents of other states

TELEHEALTH STATE STANDARDS

TELEHEALTH STATE STANDARDS

- Some states have laws defining telehealth and proscribing how it can be used, for example:
  - Informed consent
  - Prescribing of controlled substances
  - Specific prohibitions of the use of telemedicine for certain services
  - Recordkeeping requirements
  - Existing physician-patient relationship
  - Modality of communication technology

CONNECTICUT GENERAL STATUTES 19A-906

- Telehealth does **not** include the use of facsimile, audio-only telephone, texting or electronic mail
- A telehealth provider shall only provide telehealth services to a patient when the telehealth provider:
  - (A) Is communicating through real-time, interactive, two-way communication technology or store and forward technologies;
  - (B) has access to, or knowledge of, the patient's medical history, as provided by the patient, and the patient's health record, including the name and address of the patient's primary care provider, if any;
  - (C) conforms to the standard of care applicable to the telehealth provider's profession and expected for in-person care as appropriate to the patient's age and presenting condition, except when the standard of care requires the use of diagnostic testing and performance of a physical examination, such testing or examination may be carried out through the use of peripheral devices appropriate to the patient's condition; and
  - (D) provides the patient with the telehealth's provider license number and contact information.

CONNECTICUT GENERAL STATUTES 19A-906

- At the first telehealth interaction with a patient, the telehealth provider must:
  - Inform the patient concerning the treatment methods and limitations of treatment using a telehealth platform.
  - Obtain the patient's consent to provide telehealth services.
  - Document such notice and consent in the patient's health record (any subsequent revocation).
- Ask the patient whether the patient consents to the telehealth provider's disclosure of records concerning the telehealth interaction to the patient's primary care provider. If the patient consents to such disclosure, the telehealth provider shall provide records of all telehealth interactions to the patient's primary care provider, in a timely manner.

CONNECTICUT GENERAL STATUTES 19A-906

Telehealth Providers are Licensed:

Physician	Physical Therapist	Chiropractor	Naturopath	Podiatrist	Occupational Therapist	Optometrist
Registered Nurse	Advanced Practice Registered Nurse	Physician Assistant	Psychologist	Marital and Family Therapist	Clinical Social Worker/Master Social Worker	Alcohol and Drug Counselor
Professional Counselor	Dietician-Nutritionist	Speech and Language Pathologist	Respiratory Care Practitioner	Audiologist	Pharmacist	Paramedic

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COVID-19 WAIVERS: EXPANSION OF TELEHEALTH TO INCLUDE AUDIO-ONLY TELEPHONE

Connecticut Executive Order 2020-7G

- audio-only telephone permitted for Medicaid providers established patients and for in-network providers for commercial fully insured health insurance for patients with whom there is an existing provider-patient relationship

March 19, 2020

Connecticut Executive Order 2020-7DD

- Permits the use of audio-only telephone telehealth for providers that are in-network providers for commercial fully-insured health insurance providing telehealth services to include those patients without an existing provider-patient relationship

April 22, 2020

Connecticut Executive Order 2020-7FF

- permit telehealth providers who are Medicaid providers providing covered telehealth services to "new or established patients" who are Medicaid recipients to engage in telehealth through the use of audio-only telephone.

April 24, 2020

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COVID-19 WAIVER

A provider who elects to provide telehealth services for a patient who is not a Medicaid beneficiary or a member covered by a fully-insured commercial plan, may engage in "telehealth" services provided that:

- Prior to engaging in such services, determine whether a patient is covered by a health plan other than Medicaid or a fully-insured commercial plan, and whether such plan provides coverage for such telehealth services. A provider who receives payment under such health plan shall not bill a patient for any additional charges beyond the reimbursement received under such health plan.
- A provider who determines that payment or coverage for telehealth services as described in this order is not available under a health plan other than Medicaid or a fully-insured commercial plan or who determines a patient is uninsured, shall accept as reimbursement for any telehealth service as payment in full, the amount that Medicare reimburses for such service, provided that if the provider determines that the patient is uninsured or otherwise unable to pay for such services, the provider shall offer financial assistance, if such provider is otherwise required to provide financial assistance under state or federal law.

COVID-19 WAIVERS: EXPANSION OF TELEHEALTH PROVIDERS

Connecticut Executive Order 2020-7G

- requirements for the licensure, certification or registration of telehealth providers shall be suspended for such telehealth providers that are Medicaid enrolled providers or in-network providers for commercial fully insured health insurance
- Any related regulatory requirement that such telehealth services be provided from a provider's licensed facility is waived

March 19, 2020

April 22, 2020

Connecticut Executive Order 2020-7DD

- dentist
- behavior analyst
- genetic counselor
- music therapist
- art therapist
- veterinarian

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HIPAA/DATA SECURITY

HIPAA COVERED ENTITY STANDARDS

- Compliant technologies
- Risk Assessments
- Policies and procedures
- Training
- Limitations on the use and disclosure of PHI
- Consents (specific to telehealth)
- Distribution of Notice of Privacy Practices
- Business Associate agreements

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HIPAA COVERED ENTITY STANDARDS

Compliant technologies - *vague*

- ”Synchronous” – at minimum interactive audio/video permitting secure two-way, real-time interactive communication between patient and practitioner
- Store-and-forward
- Security Rule and NIST standards – End-to-end encryption
  - No intermediate server, *unless...*
  - ePHI use of Advanced Encryption Standard (“AES”) 128, 192, or 256-bit
  - 256-bit standard at rest and in remote monitoring/storage devices
  - 128-bit video and ”in motion”
  - User authentication

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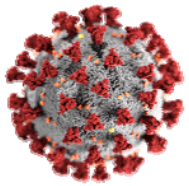
HIPAA COVERED ENTITY STANDARDS

Consent – *Public Act No. 15-88*

- At the time of the telehealth provider's first telehealth interaction, shall:
  - Inform the patient concerning methods, limitations
  - Obtain consent
  - Document notice and consent in health record
- Each visit:
  - Verbal consent to disclosure of records of telehealth to primary care provider

COVID-19



Modified § 19a-906(f) to permit providers enrolled in Medicaid or commercial plans to follow HHS and OCR approach to HIPAA:

OCR Notification of Enforcement discretion:

- Acknowledges that some technologies and manner they are used may not fully comply with HIPAA
- OCR will not impose penalties for noncompliance
  - including lack of Business Associate Agreement
- Any "non-public facing communication products" for any type of telehealth service.
  - Popular applications: Zoom, FaceTime, Skype

- Recommended: notify patients of potential privacy risks, enable any available encryption

Misconceptions/Contradictions:

- Does not negate causes of action related to mishandling PHI
- See OCR and HHS February 2020 Bulletin: HIPAA Privacy and Novel Coronavirus

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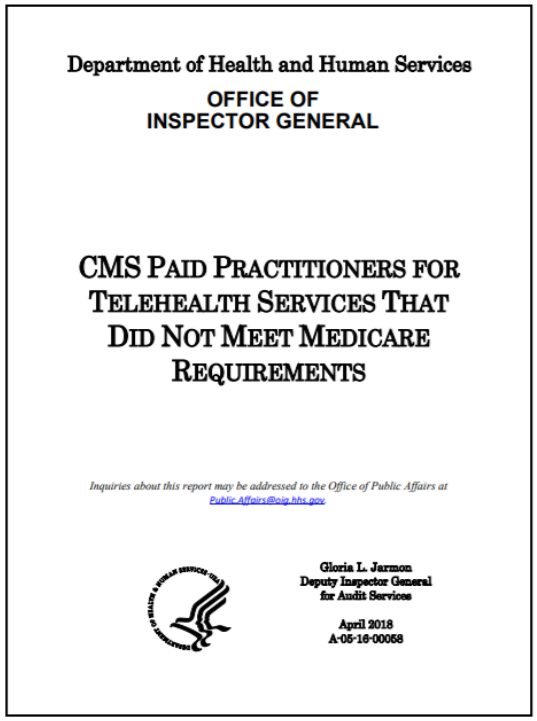
FRAUD & ABUSE ISSUES

FRAUD AND ABUSE

- False Claims Act
- Stark Law
- Anti-Kickback Statute
- Civil Monetary Penalty Law
- OIG Advisory Opinions

REIMBURSEMENT PITFALLS: OIG LESSONS LEARNED

- **April 2018 HHS-OIG Report – *CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements***
  - https://oig.hhs.gov/oas/reports/region5/51600058.asp
  - "Medicare paid a total of $17.6 million in telehealth payments in 2015, compared with $61,302 in 2001."
  - OIG's objective in the review was to determine whether CMS paid providers for telehealth services that met Medicare requirements.
  - OIG pulled a stratified random sample of 100 claims to determine whether services were reimbursable under Medicare.



Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS PAID PRACTITIONERS FOR TELEHEALTH SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov

Gloria L. Jarmon
Deputy Inspector General
for Audit Services

April 2018
A-05-16-00058

REIMBURSEMENT PITFALLS: OIG LESSONS LEARNED

- **What OIG found:**
  - 69 of 100 claims in OIG's sample met requirements for telehealth services.
  - 31 of 100 telehealth claims paid did not meet Medicare requirements:
    - beneficiaries received services at non-rural originating sites
    - claims were billed by ineligible institutional providers
    - services were provided to beneficiaries at unauthorized originating sites
    - services were provided by an unallowable means of communication
    - claims were for non-covered service
    - services were provided by a physician located outside of the U.S.

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FALSE CLAIMS ACT (31 U.S.C. 3729 ET SEQ.)

- **Prohibits**
  - (1) submitting false claims for payment to U.S.
  - (2) submitting false statements in support of false claims
  - (3) improperly retaining funds to which U.S. is entitled (e.g., failing to repay overpayments)
- **Violation where party had actual knowledge, or acted with reckless disregard or deliberate ignorance, of falsity.**
- **Cases often initiated by whistleblowers under FCA's *qui tam* provisions.**
- **Violations can lead to sanctions and exclusion by HHS-OIG.**

ANTI-KICKBACK STATUTE ("AKS") 42 U.S.C. § 1320A-7B(B)

- Prohibits offering/giving anything of value to another person/entity to induce them to refer patients, to order goods/services, or to recommend the ordering of goods/services
- Prohibits requesting anything of value in exchange for referring patients, ordering goods/services, or recommending goods/services
- Various regulatory safe harbors can protect arrangements if strictly complied with (see 42 C.F.R. § 1001.952)
- Claims resulting from AKS violations are FCA violations

STARK LAW 42 U.S.C. § 1395NN

- Strict liability administrative law
- Prohibits financial relationships between physicians and entities to which they refer for inpatient and outpatient hospital and other specified services
- Prohibits billing of Medicare/Medicaid for services rendered to patients referred by physicians with prohibited relationships
- Violations render claims submitted to Medicare/Medicaid false, in potential violation of FCA

ENFORCEMENT RISK: RECENT EXAMPLES

- **Georgia Fraud Case** – JI Medical Inc., a DME provider, paid kickbacks to doctors who ordered medical equipment based on telemedicine consultations- but the consultations allegedly never occurred. Over 20 defendants charged and $470 million in fraud alleged.
- **February 8, 2019 OIG Self-Disclosure** – Highland Rivers Community Service Board, d/b/a Highland Rivers Health in Georgia agreed to pay $133,067.26 for allegedly violating the CMP Law by submitting or causing the submission of claims for psychiatric telehealth services provided to Medicare beneficiaries at certain Highland Rivers locations when the locations were not eligible for Medicare telehealth reimbursement because they were not "originating sites."
- **January 17, 2019 OIG Self-Disclosure** - Ironton-Lawrence County Community Action Organization, Inc., Ohio, agreed to pay $99,683.77 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that Ironton-Lawrence submitted claims to Medicaid for telepsychiatry services from a service site that was not approved under Ironton-Lawrence's scope of project.

BLANKET WAIVERS OF SECTION 1877(G) OF THE SOCIAL SECURITY ACT DUE TO DECLARATION OF COVID-19 OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY

- Effective March 1, 2020
- The blanket waivers apply only to financial relationships and referrals that are related to the national emergency that is the COVID-19 outbreak in the United States.
- Purpose:
  - (1) sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and CHIP programs;
  - (2) health care providers that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of section 1877 of the Act and regulations thereunder as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the government's determination of fraud or abuse

COVID-19 WAIVER

- 18 Different Waivers, Including:
  - Remuneration from an entity to a physician (or an immediate family member of a physician) that is above or below the fair market value for services personally performed by the physician (or the immediate family member of the physician) to the entity.
  - Rental charges paid that are below fair market value for the entity's lease of office space from the physician (or the immediate family member of the physician).
  - Rental charges paid that are below fair market value for the entity's lease of equipment from the physician (or the immediate family member of the physician).
  - Remuneration from that is below fair market value for items or services purchased by the entity from the physician (or the immediate family member of the physician).
  - Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in 42 CFR 411.357(m)(5).
  - Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of nonmonetary compensation that exceeds the limit set forth in 42 CFR 411.357(k)(1).
  - Remuneration from an entity to a physician (or the immediate family member of a physician) resulting from a loan to the physician (or the immediate family member of the physician): (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.

COVID-19 WAIVERS

A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.

To accommodate patient surge, a hospital rents office space or equipment from an independent physician practice at below fair market value or at no charge.

A hospital or home health agency purchases items or supplies from a physician practice at below fair market value or receives such items or supplies at no charge.

A hospital provides free use of medical office space on its campus to allow physicians to provide timely and convenient services to patients who come to the hospital but do not need inpatient care.

An entity provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.

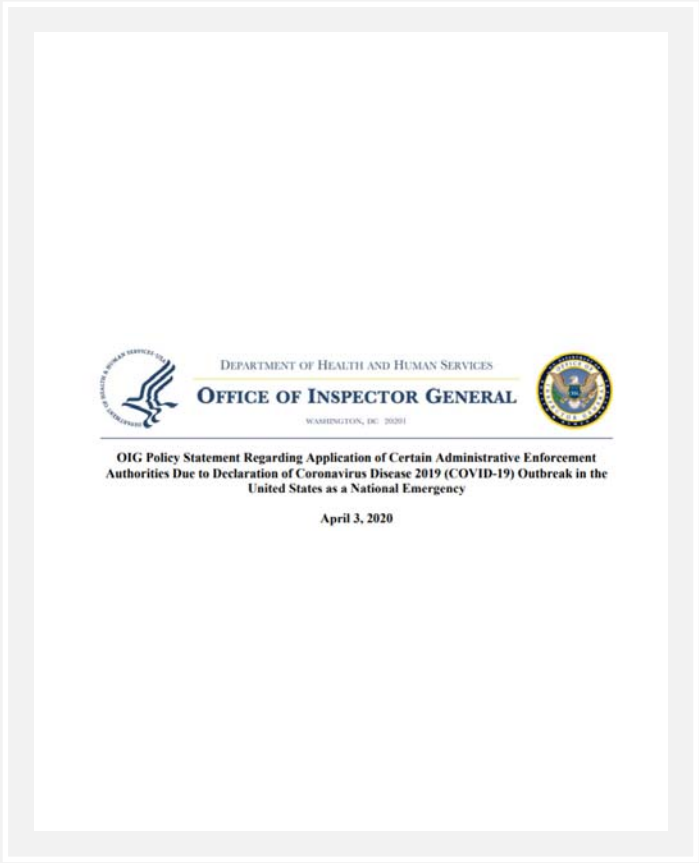
An entity sells personal protective equipment to a physician, or permits the physician to use space in a tent or other makeshift location, at below fair market value (or provides the items or permits the use of the premises at no charge).

A physician in a group practice whose principal medical practice is office-based orders radiology services that are furnished by the group practice to a Medicare beneficiary who is isolated or observing social distancing in the beneficiary's home, provided that the group practice satisfies all of the requirements of 42 CFR 411.352.

A hospital sends a hospital employee to an independent physician practice to assist with staff training on COVID-19, intake and treatment of patients most appropriately seen in a physician office, and care coordination between the hospital and the practice.

A hospital provides meals, comfort items (for example, a change of clothing), or onsite child care with a value greater than $36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak in the United States.

An entity provides nonmonetary compensation to a physician or an immediate family member of a physician in excess of the $423 per year limit (per physician or immediate family member), such as continuing medical education related to the COVID-19 outbreak in the United States, supplies, food, or other grocery items, isolation-related needs (for example, hotel rooms and meals), child care, or transportation.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency

April 3, 2020

- Effective April 3, 2020
- In response to the unique circumstances resulting from the COVID-19 outbreak and the Secretary's COVID-19 Declaration, the Office of Inspector General (OIG) issues this Policy Statement to notify interested parties that OIG will exercise its enforcement discretion **not** to impose administrative sanctions under the Federal anti-kickback statute for certain remuneration related to COVID-19 covered by the Blanket Waivers of Section 1877(g) of the Social Security Act (the Act) issued by the Secretary on March 30, 2020 (the Blanket Waivers), subject to the conditions specified herein.

COVID-19 WAIVER FAQ

- Can a hospital provide access to its existing HIPAA-compliant, web-based telehealth platform for free to independent physicians on its medical staff to furnish medically necessary telehealth services during the time period subject to the COVID-19 declaration?

- We recognize that access to the platform would provide independent value to the physicians-who may refer Federal health care program business to the hospital-and therefore would implicate the Federal anti-kickback statute. Nonetheless, in the unique and exigent circumstances resulting from the COVID-19 outbreak, we believe that free access to a hospital's telehealth platform by physicians on its medical staff would present a low risk of fraud and abuse under the Federal anti-kickback statute and could improve beneficiaries' access to telehealth services, so long as the platform is (i) provided for free to physicians to furnish medically necessary telehealth services; (ii) provided only when necessary as a result of the COVID-19 outbreak and during the period subject to the COVID-19 Declaration; (iii) not conditioned on the physician's past or anticipated volume or value of referrals to, or other business generated for, the hospital for any items or services that may be reimbursable in whole or in part by a Federal health care program; and (iv) offered to all physicians on the medical staff on an equal basis (but not necessarily accepted by every member to whom it is offered).

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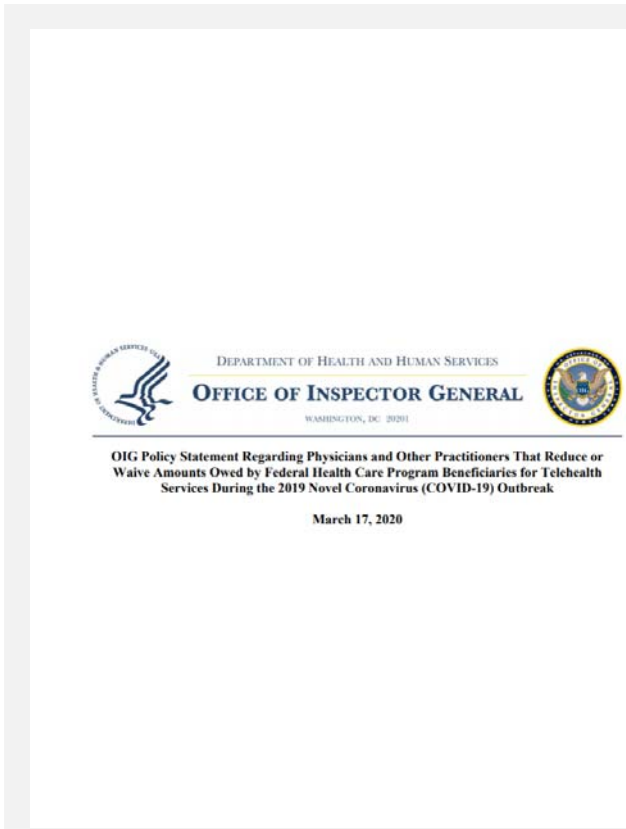

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak

March 17, 2020

- Ordinarily, if physicians or practitioners routinely reduce or waive costs owed by Federal health care program beneficiaries, including cost sharing amounts such as coinsurance and deductibles, they would potentially implicate the Federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries.
- The policy statement notifies providers that OIG will **not** enforce these statutes if providers choose to reduce or waive cost-sharing for telehealth visits during the COVID-19 public health emergency, which the HHS Secretary determined exists and has existed since January 27, 2020.
- OIG intends for the Policy Statement to apply to a broad category of non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring.

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REIMBURSEMENT

MEDICARE REIMBURSEMENT

Required Elements:

- Originating Site
- Distant Site
- Technology
- Approved Service

Billing - (02 place of service)

Enrollment – Enroll where physically located and where the patient is located

MEDICARE REIMBURSEMENT: BILLING

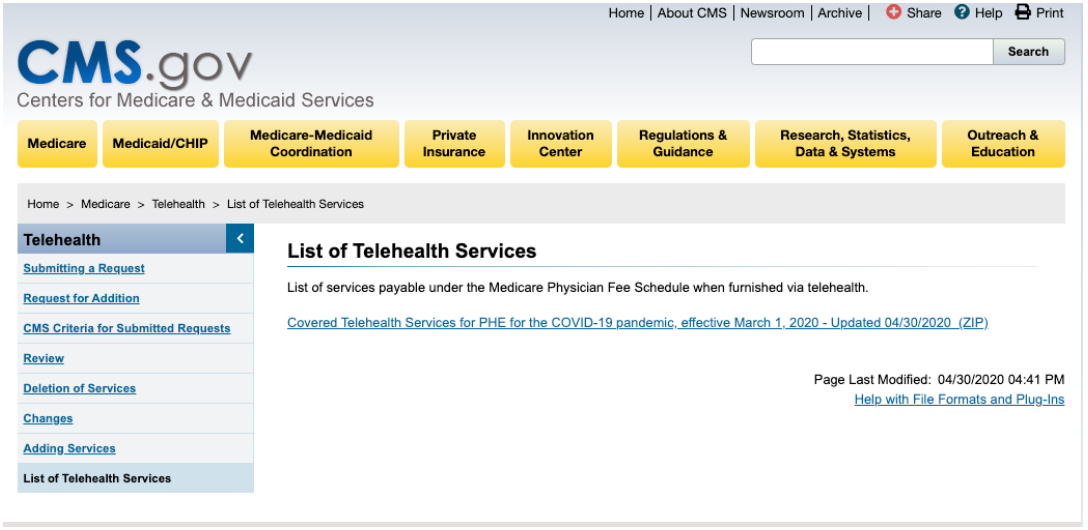
Distant site practitioners

- CPT Code or HCPS Code for service
- Use place of service code (02)

Originating site facility fee (Q3014)

- Use the "office" place of service code (11)

Special coverage rules may apply: Check CMS.Gov List of Telehealth Services



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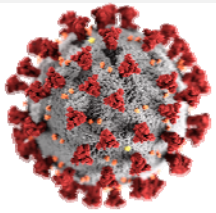
MEDICARE REIMBURSEMENT: COVID

- Rapid expansion of qualifying services
- Removal of Originating Site restriction around home and non-HPSA/HRSA sites
- Waived limitations on providers eligible for reimbursement
  - counselors, physical therapists, audiologists
- FQHCs, rural health clinics, and hospice now eligible for telehealth reimbursement

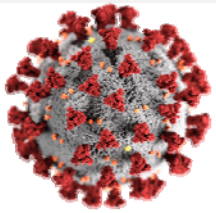


Recommended Reference: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

- Medicare Telemedicine Healthcare Provider Fact Sheet
- Telemedicine Toolkits
  - Long-term Care
  - Coronavirus

MEDICAID REIMBURSEMENT

- Before COVID – Partial Parity
- limited services covered
- No restriction on type of Originating Site
- Certain services require showing of good cause (clinical appropriateness), likelihood to expand access, and/or prior authorization



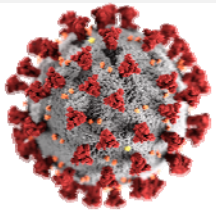
Recommended Reference: CMAP COVID-19 Response Bulletin 1 and subsequent Bulletins

Since COVID (Executive Orders 7G, 7DD and 7FF and bulletins):

- Expand to various new practitioners and services
- Reimbursement equal to in-person
- Waive licensure and registration requirements
- Added specific “new patient” reimbursable E&M services
- MAT and behavioral covered
- Waiver of prior authorization requirements for multiple services

COMMERCIAL INSURANCES

- Before COVID – Partial Parity
- limited services covered
- No restriction on type of Originating Site
- Certain services require showing of good cause (clinical appropriateness), likelihood to expand access, and/or prior authorization



Since COVID (Executive Orders 7G, 7DD and 7FF):

Providers who receive payment under commercial health plans cannot balance bill patients for additional charges.

If uninsured – must accept no more than Medicare allowable and offer financial assistance.

Will not accept out-of-state licensure.

Waive prior authorization on a case-by-case basis.

WHAT'S NEXT?

EXPECT CONTINUING STATE AND FEDERAL DEREGULATION AND REGIONAL ALIGNMENT

The NY Approach: Insurer may not exclude a service that is otherwise covered under the plan because the service is delivered via telehealth

Telehealth services reimbursed at parity with existing off-site visit payments (clinics) or F2F visits (100% of Medicaid rates)

New E&M service codes for at-home testing, screening, and monitoring specific to COVID and new "homebound" care considerations.

Long-term adoption of telehealth for safety, not merely retention

FROM AN OPERATOR'S PERSPECTIVE

Executive Orders create region alignment – states like CT, MA, NH now following more traditionally progressive "early adopter" states

Certain relaxations, mixed messaging, and lack of expertise create marketplace uncertainty and safety concerns during increased adoption

HIPAA and data security, licensure "snap-back"

Special Registration or permanent deregulation for controlled substances prescribing

QUESTIONS